COVIDIEN

510(k) Summary K130357
Covidien llc, dba superDimension Inc.
SuperDimension® Triple Needle Cytology Brush

Date Prepared: 11/4/2013

510(k) Applicant: Covidien llc, formerly registered as superDimension Inc.
161 Cheshire Lane Suite 100
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NOV 06 2013

Name of Device :
Trade Name : superDimension® Triple Needle Cytology Brush
Common Name: Bronchial Biopsy Brush
Classification Name: Bronchoscope (flexible or rigid) and accessories
21 CFR Part 874.4680
Product code: BTG

Equivalent Legally-Marketed Devices:
K834402 Gastrointestinal Sheath Brush (KOG) by Hobbs Medical, Inc.
K944650 Wang Bronchial Needle Brush (EOQ) by ConMed

Description:
The superDimension® Triple Needle Cytology Brush is designed to obtain tissue samples for biopsy from endobronchial lesions, peripheral lung nodules, or lung masses. The superDimension® Triple Needle Cytology Brush is an endoscopic catheter comprised of an outer Ethylene Tetrafluoroethylene (ETFE) sheathing and an inner catheter assembly. The inner catheter assembly consists of a thumb ring at the proximal end and a twisted wire shaft to connect to the distal end. The distal end terminates in three connected brushes available in two lengths: 10 mm and 15mm. The brushes have sharpened ends, referred to as needle-tipped, that can be used to rough up tissue to obtain a sample of tissue or cells. When the catheter is inserted into a channel such as a bronchoscope or superDimension Extended Working Channel (EWC) with the distal brush in a retracted position inside the outer sheath. When the catheter is in position, the brushes can be extended into the tissue to obtain tissue samples by advancing the proximal thumb ring. When the physician believes that an adequate sample has been taken, the brushes are retracted back into the sheath and then the entire catheter is withdrawn from the channel for standard tissue analysis. The superDimension® Triple Needle Cytology Brush is similar to currently marketed cytology brushes except that it has three smaller brushes in place of one larger brush.

Intended Use:
To be utilized through a flexible endoscope or the superDimension system by physicians who are trained in endoscopic techniques for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

Summary of Substantial Equivalence:
The superTrax Triple Needle-Tipped Cytology brush is substantially equivalent to the ConMed Needle-Tipped Cytology Brush and the Hobbs Cytology Brush predicate devices in the following attributes:

- Indications for Use
- Mechanism of action
- Length
- Sterilization technique
- Performance Characteristics
- Design
- Size
- Materials
- Packaging

The difference between the predicate devices and the superDimension Triple Needle Cytology Brush is that the predicate devices have one, larger brush on the distal end compared to three smaller, flexible brushes on the distal end of the superDimension Triple Needle Cytology Brush.

Performance Data:
In-vitro and in-vivo testing has been performed on all components, subassemblies, and /or full devices. The results showed that the device met the required specifications for the completed tests and performed similarly to the predicate devices. Testing included the following:

- In Vitro Testing
  - Radiographic Testing
  - Catheter Tensile Testing
  - Dimensional Testing
  - Simulated Use Testing
  - Trackability Testing
  - Shelf Life Testing per ASTM F1980-07, ASTM F2096-11, and ASTM F88-09
  - Distribution Testing per ASTM D4169-09
  - Sterilization Testing per ISO 11135-1
  - Biocompatibility Testing (cytotoxicity, irritation, sensitization) per ISO 10993-1, ISO 10993-5, ISO 10993-7, ISO 10993-10
- In Vivo Testing in a porcine model
  - Tissue Collection
  - Safety Testing

Clinical Data:
Clinical tests were not required to validate the design of the SuperDimension® Triple Needle Cytology Brush due to the extensive history of similar devices.

Conclusion:
Based on the intended use, technological characteristics, and results from safety and performance testing, the superDimension Triple Needle Cytology Brush is substantially equivalent to the legally marketed predicate devices, Gastrointestinal Sheath Brush (KOG) by Hobbs Medical, Inc. K834402, and the Wang Bronchial Needle Brush (EOQ) by ConMed K944650.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

November 6, 2013

Covidien Llc
c/o Ms. Deborah Fleetham
Manager, Regulatory Affairs
161 Cheshire Lane, Suite 100
Minneapolis, MN 55441

Re: K130357
Trade/Device Name: Superdimension Triple-Needle Cytology Brush
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: BTG
Dated: September 27, 2013
Received: September 30, 2013

Dear Ms. Fleetham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130357

Device Name: superDimension® Triple Needle Cytology Brush

Indications For Use:

To be utilized through a flexible endoscope or the superDimension system by physicians who are trained in endoscopic techniques for retrieving specimens from patients with endobronchial lesions, peripheral lung nodules, or lung masses.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Sunny Park